ACTA ORTHOPAEDICA et TRAUMATOLOGICA TURCICA
www.aott.org.tr

Research Article

Effects of Kinesio Taping on pain, paresthesia, functional status, and overall health status in patients with symptomatic thoracic outlet syndrome: A single-blind, randomized, placebo-controlled study

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ARTICLE INFO

Article history:
Submitted 23 January 2019
Received in revised form
30 October 2019
Accepted 30 March 2020
Available Online Date
21 May 2020

Keywords:
Kinesio tape
Kinesio taping
Pain
Thoracic outlet syndrome

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ABSTRACT

Objective: This study aimed to assess the effects of kinesio taping (KT) on pain, paresthesia, functional status, and overall health status in patients with symptomatic thoracic outlet syndrome (sTOS).

Methods: A single-blind placebo-controlled design was employed in this study. The study duration was defined as 12 months. Analyses were performed on 60 patients with sTOS randomly assigned to KT (4 men and 26 women; mean age=33.5 years, range=20–46 years) and control groups (5 men and 25 women; mean age=26 years, range=20–43 years). KT was applied to the KT group three times. The control group received placebo taping. Pain and paresthesia were evaluated using the visual analogue scale (VAS) pain (10 cm) and VAS paresthesia (10 cm). The upper limb function was assessed using the disabilities of the arm, shoulder, and hand (DASH) questionnaire. The overall health status was evaluated based on the Nottingham Health Profile (NHP). Each assessment was carried out at baseline (t0), posttreatment (t1), and 8 weeks after baseline (t2).

Results: In the KT group, except the social isolation domain of the NHP, all outcome measures showed improvement from t0 to t1. At the second follow-up visit (t2), improvements remained visible compared with baseline. However, none of the variables improved from t1 to t2. Otherwise, all measures deteriorated slightly, and the deteriorations in VAS for pain, NHP pain, NHP sleep, and NHP physical abilities were statistically significant (p=0.041, p=0.048, p=0.013, and p=0.016, respectively). In the control group, only VAS for paresthesia and NHP emotional reaction showed improvement over time (p=0.002 and p=0.044, respectively). When changes in outcome measures between the two groups were compared, except NHP emotional reaction and NHP social isolation, median changes (from t0 to t1) were higher in the KT group than in the control group (p<0.05 for all variables). Regarding VAS pain, VAS paresthesia, DASH, and three NHP domains (energy level, pain, and physical abilities), changes from t0 to t2 were also higher in the KT group (p<0.05 for all variables).

Conclusion: KT can provide benefits in terms of relieving pain and paresthesia, as well as improving the upper limb function and quality of life in patients with sTOS.

Level of Evidence: Level II, Therapeutic study

Thoracic outlet syndrome (TOS) is a symptom complex related to the compression of the neurovascular bundle at the cervicothoracic junction (1). Anatomical pathologies including cervical rib, hypertrophied scalene muscle, wide transverse process of the C7 vertebra, rudimentary first rib/first rib exocytosis, bifid clavicula, and aberrant fibromuscular bands are common causes of TOS. The interscalene triangle, subcoracoid region, and costoclavicular space are the potential areas of compression (2-5).

TOS can be classified as vascular TOS and neurogenic TOS according to the compressed anatomic structures. Neurogenic TOS can further be classified as true neurogenic TOS and symptomatic (nonspecific) TOS (sTOS) (3). TOS is 95%-98% neurogenic in origin, mostly as sTOS (4). The diagnosis of sTOS depends on anamnesis and physical examination. Cervical radiographs can reveal anatomic variations. Magnetic resonance imaging has low specificity and sensitivity for TOS diagnosis,

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Cite this article as: *Aygül Ortaç E, Sarpel T, Coşkun Benlidayı İ. Effects of Kinesio Taping on pain, paresthesia, functional status, and overall health status in patients with symptomatic thoracic outlet syndrome: A single-blind, randomized, placebo-controlled study. Acta Orthop Traumatol Turc 2020; 54(4): 394-401.*

DOI: 10.5152/j.aott.2020.19042

whereas electroneuromyographic findings are usually nonspecific (5).

First-line treatment for sTOS is conservative and includes patient education, behavioral modification for postural correction, exercise, electrotherapy agents, and manual therapy (6, 7). Patients irresponsive to conservative regimen might be candidates for scalene muscle chemodenervation (either with lidocaine or botulinum toxin) or surgery (7).

Kinesio taping (KT) is a widely used conservative treatment option for several musculoskeletal conditions. Kinesio tapes are made from cotton fibers and do not contain any pharmacological molecules. KT has been used to modulate pain, inflammation, muscle activity, and circulation for disorders of the cervical region and shoulder (8, 9). However, data regarding the potential effectiveness of KT in TOS are scarce.

With the abovementioned knowledge, the objective of the present study was to evaluate the effectiveness of KT on 1) clinical variables, 2) upper extremity functionality, and 3) general health status/health-related quality of life in patients with sTOS.

Materials and Methods

Study population

Patients aged >18 years and clinically diagnosed with sTOS with symptoms present for at least 3 months were included in the study. The presence of at least three of the following four clinical criteria was required for diagnosis (10): 1) pain/paresthesia in the arm/hand, 2) symptom aggravation with arm elevation, 3) tenderness above the clavicula and over the brachial plexus, and 4) positive elevated arm stress test (10, 11).

Exclusion criteria were determined as 1) presence of cervical radiculopathy/myelopathy, 2) history of surgery to the cervical spine, 3) presence of any inflammatory rheumatic disease, 4) entrapment neuropathies of the upper extremity, 5) history of major trauma to the head/neck, 6) any malignity, and vii) history of physical therapy/injection during the last 3 months. Each patient was evaluated by a physician to rule out the exclusion criteria. Further radiologic evaluation was performed when necessary. Patients with radiological signs of the abovementioned conditions were excluded.

HIGHLIGHTS

- The KT application provided benefit in terms of relieving pain and paresthesia, improving upper extremity functionality, and health-related quality of life in patients with sTOS.
- The effectiveness was apparent in the short term and slightly decreased with time.
- No additional therapeutic benefit was obtained after the removal of KT material.
- In daily clinical practice, KT application might be considered as a conservative treatment option for sTOS, particularly for the short term.

Study design and protocol

A prospective, randomized, placebo-controlled design was applied. The study duration was set as 12 months. Ethical approval was obtained from the Local Ethics Committee of Çukurova University (February 5, 2016; no. 50/13).

The study participants were randomized into KT and control groups according to a computer-based randomization sequence. Each patient was informed about the study protocol. Written informed consent was obtained from all patients prior to the procedure. Verbal patient education on behavioral modification techniques for ergonomics and postural correction was provided to both groups. KT was applied to the experimental group three times. Each application lasted 4 days with a total KT duration of 12 days. The control group received placebo KT in addition to patient education. No additional pharmacological or nonpharmacological approach that might interfere with the outcome measures was tailored to the participants. The patients were blinded to the study arms throughout the follow-up period.

KT procedure

Kinesio® Tex Gold™ (Kinesio Holding Corp., Albuquerque, U.S.) was used as the taping material. The skin was cleaned prior to the application to remove oils, lotions, and moisture, which might limit the ability of the adhesive to adhere. The KT procedure was modified from the technique described by Kase et al. and performed by a certificated physician. The application technique of KT is demonstrated by a video (Supplementary video) (12). To relieve tension over the compression site, the muscle inhibition technique was applied. The application targeted four muscles: subclavian, pectoralis minor, biceps, and anterior scalene. Four kinesio strips were prepared prior to application: three Y-shaped strips and one I-shaped strip. The procedure included four steps as described below (Figure 1).

1) The base of the I-shaped strip was placed just below the acromioclavicular joint, and the strip was directed from the insertion of the subclavian muscle to its origin. The shoulder was positioned abducted and externally rotated, the strip was applied along the inferior aspect of the clavicula with 15%-25% tension (very light to light tension), and the inferior tail of the strip was placed 2.5-3 cm below the sternoclavicular joint with no tension.

2) The superior tail of the first Y-shaped strip was applied over the coracoid process with no tension and directed from the insertion to the origin of the pectoralis minor muscle. With 15%-25% tension, the first and second arms of the

Y-shaped strip were directed toward the third and fifth costochondral joints, respectively, and then placed over the related joint with no tension at the distal end.

3) The second Y-shaped strip was prepared for the biceps muscle. The distal end of the strip was placed 5 cm below the antecubital space without tension. The medial tail of the strip (with 15%-25% tension) was applied along the short head of the biceps, and the distal end was placed over the coracoid process of the scapula without any tension. The other tail of the strip was applied along the lateral border of the biceps long head with 15%-25% tension. The lateral arm of the strip was placed over the supraglenoid tuberosity of the scapula with no tension.

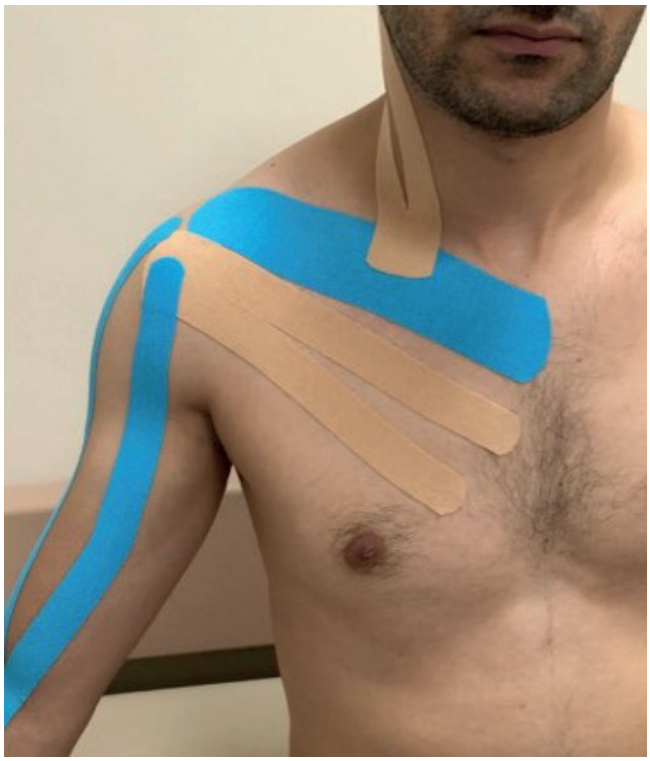

Figure 1. Application technique of KT

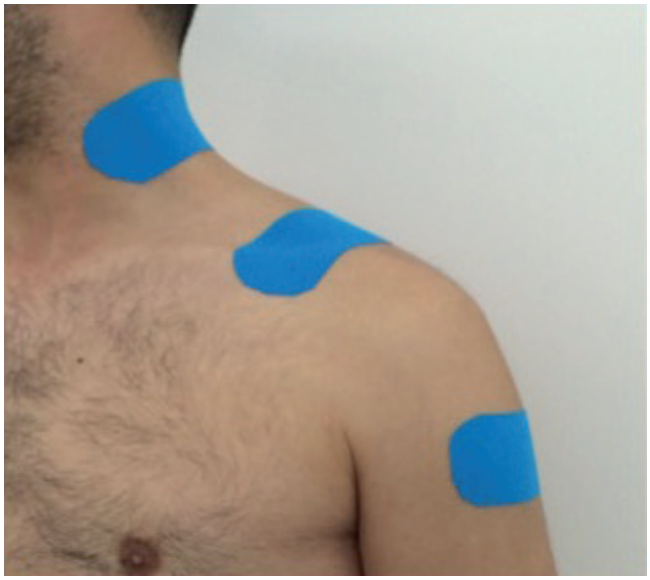

Figure 2. Application technique of placebo KT

4) The last Y-shaped strip was applied to the anterior scalene muscle. The head of the patient was laterally flexed against the contralateral side. The base of the strip was placed over the medial side of the first rib. The medial arm of the strip was applied with very light tension (10%–15%) toward the C3-C6 transverse processes. The lateral arm of the strip was placed toward the anterior border of the scalene muscle (12).

Placebo KT was performed by using three I-shaped strips. The strips were applied with no tension and perpendicular to the axes of KT applications used in the experimental group (Figure 2).

Follow-up procedure and outcome measures

The patients were evaluated prior to the intervention (t0), just after the removal of the third tape (t1), and 8 weeks after baseline (t2). The outcome measures were pain and paresthesia, upper extremity functionality, and general health perception.

1) Pain and paresthesia were evaluated by the visual analogue scale (VAS) pain (10 cm) and VAS paresthesia (10 cm). Ten-centimeter horizontal scales were used for each symptom, on which 0 represented "no pain/paresthesia at all" and 10 referred to "the worst pain/paresthesia ever possible."

2) The upper extremity functionality was assessed by the Turkish validated version of the disabilities of the arm, shoulder, and hand (DASH) questionnaire (13, 14). The questionnaire consisted of three sections, including the disability/symptom section and two optional sections. The disability/symptom section was used in this study. This section questioned the difficulties in daily living activities and symptom severity via 30 items. A 5-point Likert scale was used in each item. Scores ranged from 0 to 100, where higher scores represented more disability.

3) General health perception/health-related quality of life was evaluated by the Turkish validated version of the Nottingham Health Profile (NHP) (15-17). The questionnaire had two parts. Part I was used in the study, which consisted of 38 items in six dimensions, including physical abilities (8 items), pain (8 items), emotional reaction (9 items), energy level (3 items), sleep (5 items), and social isolation (5 items). Each question was answered as Yes or No and assigned a weighted value. Scores for each dimension ranged from 0 to 100, where 0 represented "no problems at all" and 100 indicated "presence of all problems within a dimension."

Statistical analysis

The statistical analysis was performed by IBM® SPSS® (Statistical Package for Social Sciences) Statistics for Windows, ver-

sion 20.0 (IBM Corp.; Armonk, NY, USA). The distribution of the variables was checked by analyzing skewness and kurtosis for each variable, as well as by using the Shapiro-Wilk test. Baseline categorical variables and continuous variables were compared between groups by Chi-square test and the Mann-Whitney U test, respectively. Within-group changes in outcome measures by time (comparison among three time values) were evaluated by using the Friedman test with further Bonferroni correction. Post hoc test was performed for pairwise comparisons. Between-group comparison of change in outcome measures was assessed by the Mann-Whitney U test.

Results

This study included 62 patients with sTOS. Each group comprised 31 patients. One patient from each group was withdrawn from the study because of skin allergy to the kinesio tape material. Therefore, the statistical analysis included a total of 60 patients (30 in each group) (Figure 3).

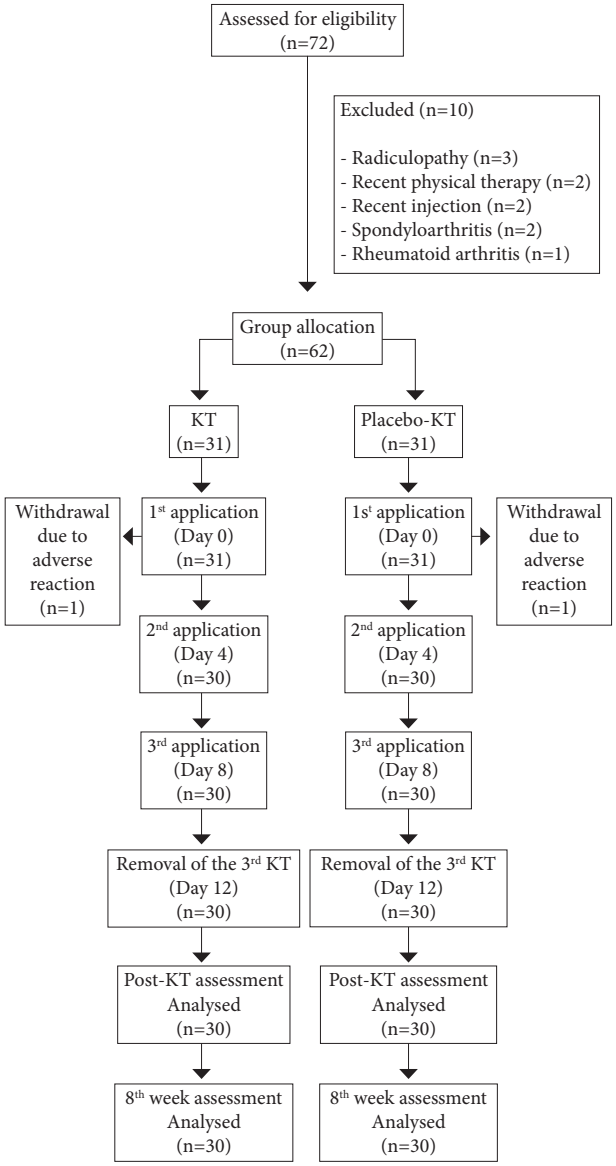

Figure 3. Flowchart of the study

Baseline characteristics of the groups are given in Table 1. Accordingly, the sociodemographic and clinical measures including VAS pain, VAS paresthesia, DASH, and NHP domains showed similarity between groups (p>0.05 for all measures).

In the KT group, all outcome measures except NHP social isolation showed statistically significant improvement from baseline to t1. At the second follow-up visit (t2), improvements remained visible compared with baseline. However, none of the variables improved from t1 to t2. Rather, all measures deteriorated slightly, and the deteriorations in VAS for pain, NHP pain, NHP sleep, and NHP physical abilities were statistically significant (p=0.041, p=0.048, p=0.013, and p=0.016, respectively). Regarding the place-

Table 1. Baseline characteristics of the groups

	KT group n=30	Placebo KT group n=30	p
Sex (male/female)[a]	4 (13.3)/ 26 (86.7)	5 (16.7)/ 25 (83.3)	0.718
Age (years)[b]	33.5 (20–46)	26 (20–43)	0.071
Employment (Yes/No)[a]	19 (63.3)/ 11 (36.7)	17 (56.7)/ 13 (43.3)	0.598
VAS for pain (cm)[b]	6 (5–10)	6 (3–8)	0.792
VAS for paresthesia (cm)[b]	5 (0–9)	5 (1–8)	>0.999
DASH (0–100)[b]	42.9 (15–55)	38.3 (11.6–56.6)	0.197
NHP energy level (0–100)[b]	66.6 (0–100)	100 (0–100)	0.429
NHP pain (0–100)[b]	31.3 (12.5–100)	50 (0–100)	0.796
NHP emotional reaction (0–100)[b]	33.3 (0–88.8)	44.4 (0–100)	0.434
NHP sleep (0–100)[b]	20 (0–60)	20 (0–100)	0.794
NHP social isolation (0–100)[b]	0 (0–80)	0 (0–100)	0.567
NHP physical abilities (0–100)[b]	25 (0–50)	25 (0–62.5)	>0.999

Results of Mann–Whitney U test/Chi-square test
DASH: the disabilities of the arm, shoulder, and hand questionnaire; KT: kinesio taping; NHP: the Nottingham Health Profile; VAS: the visual analogue scale
[a]Represents n (%); [b]Represents median (min–max)

Table 2. Between-group comparison of changes in outcome measures over time

	t0-t1		t1-t2		t0-t2	
	KT	Placebo KT	KT	Placebo KT	KT	Placebo KT
VAS for pain (0–10)	3 (0–10)***	0 (-3 to 6)	-1 (-6 to 4)	0 (-3 to 2)	2.5 (-1 to 8)***	0 (-1 to 6)
VAS for paresthesia (0–10)	3 (-1 to 7)*	1 (-1 to 8)	0 (-4 to 3)	0 (-5 to 3)	2 (-1 to 6)*	0 (-1 to 6)
DASH (0–100)	17.6 (-5.8 to 45.8)***	1.6 (-14.4 to 23.3)	0 (-28.3 to 23.3)	-0.4 (-15 to 17.5)	8.8 (-18.3 to 47.5)***	-0.6 (-17.44 to 17.44)
NHP energy level (0–100)	33.3 (-33.3 to 100)**	0 (-33.4 to 66.7)	0 (-66.6 to 33.4)	0 (-66.7 to 33.4)	33.3 (-66.7 to 100)***	0 (-33.4 to 33.4)
NHP pain (0–100)	12.5 (-12.5 to 100)***	0 (-25 to 25)	0 (-75 to 37.5)	0 (-25 to 37.5)	12.5 (-37.5 to 100)**	0 (-25 to 37.5)
NHP emotional reaction (0–100)	11.1 (-33.3 to 55.5)	0 (-22.2 to 44.4)	0 (-44.5 to 33.3)	0 (-66.6 to 22.2)	11.1 (-22.3 to 44.4)	0 (-22.2 to 55.5)
NHP sleep (0–100)	10.0 (0–60)*	0 (-20 to 40)	0 (-60 to 20)**	0 (-80 to 80)	0 (-60 to 40)	0 (-60 to 60)
NHP social isolation (0–100)	0 (-20 to 20)	0 (-20 to 40)	0 (-20 to 20)	0 (0-20)	0 (-20 to 40)	0 (-20 to 60)
NHP physical abilities (0–100)	12.5 (-12.5 to 50)***	0 (-37.5 to 25)	-12.5 (-50 to 37.5)*	0 (-12.5 to 25)	12.5 (-37.5 to 25)**	0 (-12.5 to 25)

Results of Mann–Whitney U test. Values are presented as median (min–max); t0-t1: change from baseline to posttreatment, t1-t2: change from posttreatment to 8th week, t0-t2: change from baseline to 8th week
DASH: the disabilities of the arm, shoulder, and hand questionnaire; KT: kinesio taping; NHP: the Nottingham Health Profile; VAS: the visual analogue scale
***p<0.001; **p<0.01; *p<0.05

bo KT group, only VAS for paresthesia and NHP emotional reaction showed improvement over time (p=0.002 and p=0.044, respectively).

Changes in outcome measures were compared between KT and placebo KT groups (Table 2). Except NHP emotional reaction and NHP social isolation, median changes in outcome measures (from t0 to t1) were significantly higher in the KT group when compared with those in the placebo. Regarding VAS pain, VAS paresthesia, DASH, and three NHP domains (energy level, pain, and physical abilities), changes from t0 to t2 were also higher in the KT group (Table 2).

Discussion

This study has three major findings to be discussed.

1. The KT application provided some benefit in terms of relieving pain and paresthesia, improving upper extremity functionality, and health-related quality of life in patients with sTOS.
2. The effectiveness was apparent in the short term and slightly decreased with time.
3. No additional therapeutic benefit was obtained after the removal of KT material.

Treating TOS in clinical practice is often challenging because patients not only present with pain and paresthesia but also experience impairment in the upper extremity functionality and general health status. Treatment options include surgical and nonsurgical approaches. Landry et al. (18) followed patients with neurogenic TOS for a mean duration of 4.2 years. Sixty-four patients were treated with conservative approaches, whereas 15 underwent surgery. The ability of returning to work was 78% and 60% in patients who were treated conservatively and with surgery, respectively. There was no difference between groups in terms of disease progression and current level of symptoms (18). There is still a debate on the optimal management of TOS. Conservative treatment includes exercise, physical modalities, behavioral modification techniques, and chemodenervation (local anesthetics, botulinum toxin A) (10, 19-21).

KT is a safe and effective treatment option for several musculoskeletal disorders (22, 23). However, it has a relatively limited therapeutic role in patients with musculoskeletal injuries (24, 25). Recently, the effectiveness of KT was evaluated in patients with shoulder impingement syndrome. Addition of KT to nonsteroidal anti-inflammatory drugs provided favorable effects on clinical outcomes (26). Reynard et al. (27) evaluated the immediate and short-term effects of KT in patients who underwent shoulder rotator cuff surgery. Although KT provided a decrease in muscle overactivity, it showed no clinical benefits in terms of pain, range of motion, and muscle strength (27). KT was also studied in entrapment neuropathies such as carpal tunnel syndrome. In the short term, KT applied with low-power laser did not provide any additional benefit. However, in the long term, hand grip strength and finger pinch strength improved significantly (28). A single-blind randomized controlled study showed that add-on KT therapy to night orthotic devices provided additional benefits in patients with carpal tunnel syndrome (29). In contrast, data regarding the potential effectiveness of KT in sTOS are scarce. Therefore, the hypothesis of the present study was set as "Regardless of any placebo effect, KT combined with patient education is more effective than patient education alone in patients with sTOS." The results confirmed this hypothesis in several ways.

Patient-reported clinical variables including pain and paresthesia, upper extremity functionality, and health-related quality of life improved after KT application. However, the improvement in NHP social isolation was not statistically significant. The therapeutic effect of KT might be explained by several mechanisms. Being related to the tension applied to the material, KT can stimulate mechanoreceptors inside the skin. The tension applied creates skin folds and thereby lifts the skin. The lifting effect of the adhesive material might not only provide a fascial correction but also cause a fluid charge from high-pressured areas to the areas with lower pressure. The increase in lymphatic and vascular flow can reduce inflammation by increased delivery of inflammatory mediators. With the resolution in edema and exudates, the pressure on the nociceptors decreases, so does the pain sensation. This domino-like sequence is considered as the underlying mechanism of the therapeutic effectiveness of KT (12, 30, 31).

With the material's salient features, the therapeutic benefits of KT might also be attributed to the placebo effect. To exclude this potential effect, the present study included a control group. The control group received placebo KT, along with the routine patient education protocol. Baseline clinical features were similar between groups. In the placebo KT group, none of the variables except VAS paresthesia and NHP emotional reaction improved by time. The improvement in paresthesia and emotional status can either be explained by the placebo effect of the KT application or be attributed to the therapeutic effect of patient education. Nevertheless, it is hard to completely exclude the potential effectiveness of placebo application. Although placebo KT was applied perpendicularly to the muscle groups and with no tension, it might still have caused some therapeutic benefit. However, between-group comparative analysis of clinical variables revealed the superiority of KT over placebo KT. Nevertheless, the effect of KT on emotional status and social isolation did not differ from the placebo. In contrast, short-term improvements in pain, upper extremity function, and other domains of general health status were observed, regardless of the placebo effect. There are a number of studies in the literature that used placebo KT for control groups (32, 33). A study on knee osteoarthritis demonstrated the superiority of KT over placebo in terms of pain relief, improvement in knee flexion, and walking tasks (32). Simsek et al. also showed that the KT group experienced more improvement in pain and upper extremity function when compared with the pretend KT group (33).

KT has some drawbacks as well. The therapeutic effect starts very early after application (34, 35). However, the effectiveness usually does not remain in the long term. In the present study, clinical variables showed a slight deterioration after the removal of the last KT until the second follow-up visit (8th week). However, compared with baseline, KT was still significantly effective on clinical parameters (except NHP sleep and NHP social isolation). Another drawback of this therapy is the potential allergic reaction to the KT material. In the current study, one patient from each group was withdrawn from the study because of skin reaction to the KT material. Both events were considered as adverse reaction. Although the material is hypoallergenic, in rare occasions, patients might react to the acrylic glue material (36). Therefore, additional attention should be paid in patients with polyacrylate allergy. Hence, it would be still hard to know and predict this issue before KT application.

This study has a number of limitations. Female dominancy and the relatively younger age distribution of the study sample might restrain us from generalizing the results to the statistical universe. However, there are strengths as well. The placebo-controlled design enabled to discriminate the therapeutic effect of KT from the potential placebo effect. There were also several distinct outcome measures, which provided a multidimensional assessment of KT therapy.

In conclusion, KT application can provide benefit in terms of relieving pain and paresthesia, improving upper extremity functionality, and improving health-related quality of life in patients with sTOS. In daily clinical practice, KT application might be considered as a conservative treatment option for sTOS, particularly for the short term.

Supplementary video: Application technique of kinesio taping for symptomatic thoracic outlet syndrome

Ethics Committee Approval: Ethics committee approval was received for this study from the Local Ethics Committee of Çukurova University (February 5, 2016; no. 50/13).

Informed Consent: Written informed consent was obtained from the patients.

Author Contributions: Concept - E.A.O., T.S., İ.C.B.; Design - E.A.O., T.S., İ.C.B.; Supervision - E.A.O., T.S., İ.C.B.; Resources - E.A.O. İ.C.B.; Materials - E.A.O., T.S., İ.C.B.; Data Collection and/or Processing - E.A.O., T.S., İ.C.B.; Analysis and/or Interpretation - E.A.O., İ.C.B.; Literature Search - E.A.O., İ.C.B.; Writing Manuscript - E.A.O., İ.C.B.; Critical Review - E.A.O., T.S., İ.C.B.

Conflict of Interest: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

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